eurofins

FINAS
Finnish Accreditation Service
S021 (EN ISO/IEC 17021-1)

QUALITY SYSTEM

# EC-CERTIFICATE

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2024.06.20 08:33:27 EEST
on: Moldsign Signature
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is valid until the
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Finnish Accreditation Service
S021 (EN ISO/IEC 17021-1)

# Attachment 1 to the Certificate number: C-02-1172-794-22

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|---|---|
| **Manufacturer:** | Labsystems Diagnostics Oy<br>Tiilitie 3<br>FI-01720 Vantaa<br>Finland |
| **Activity and product category:** | Design, manufacture and final inspection of reagents and reagent products for detection and quantification of toxoplasmosis.<br>GMDN-code(s): 52441, 52440, 52436, 60897 |
| **Products:** | The certificate covers the following products: |

| *Name* | *Model* |
|---|---|
| Neonatal Toxoplasma gondii IgM FEIA | 6199802 |
| Neonatal Toxoplasma gondii IgM EIA | 6199804 |
| Toxoplasma gondii IgG EIA | 6600100 |
| Toxoplasma gondii IgG Avidity EIA | 6600140 |

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|---|---|
| **Date:** | Valid from: 25 May 2022 |

Aliisa Siljander

Riikka Kylväjä

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# Attachment 2 to the Certificate number: C-02-1172-794-22

| | |
|---|---|
| **Manufacturer:** | Labsystems Diagnostics Oy<br>Tiilitie 3<br>FI-01720 Vantaa<br>Finland |
| **Activity and product category:** | Design, manufacture and final inspection of reagents and reagent products for diagnosing phenylketonuria.<br>GMDN-codes: 58960,53512, 53513, 58190, 58191, 58192, 58193 |
| **Products:** | The certificate covers the following products: |

| *Name* | *Model* |
|---|---|
| Neonatal Phenylalanine | 6199895 |
| | 6199896 |
| | 6199897 |
| Neonatal Phenylalanine calibrators | 6190940 |
| Neonatal Phenylalanine controls | 6190930 |
| NeoMass AAAC | 7100100 |
| NeoMass AAAC 3.0 | 7100120 |
| NeoMass AAAC Plus | 7100110 |
| NeoMass AAAC DBS Controls | 710010003 |
| NeoMass AAAC Internal Standard, Labeled Amino Acids | 710010004 |
| NeoMass AAAC Extraction Solution | 710010008 |
| NeoMass AAAC Eluent Solution | 710010009 |
| NeoMass AAAC Plus DBS Controls | 710011003 |
| NeoMass AAAC Plus Internal Standard, Labeled Amino Acids | 710011004 |
| NeoMass AAAC Plus Extraction Solution B | 710011009 |
| NeoMass AAAC Plus Eluent Solution | 710011010 |

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|---|---|
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# Attachment 3 to the Certificate number: C-02-1172-794-22

| | |
|---|---|
| **Manufacturer:** | Labsystems Diagnostics Oy<br>Tiilitie 3<br>FI-01720 Vantaa<br>Finland |
| **Activity and product category:** | Design, manufacture and final inspection of reagents and reagent products for determining chlamydia.<br>GMDN-codes: 50733, 50737, 50741, 50721, 50719, 50768, 50773, 50727, 58957 |
| **Products:** | The certificate covers the following products: |

| *Name* | *Model* |
|---|---|
| Chlamydia pneumoniae IgM EIA | 6111320 |
| Chlamydia pneumoniae IgG EIA | 6111300 |
| Chlamydia pneumoniae IgA EIA | 6111310 |
| Chlamydia pneumoniae IgG/IgM Micro-IF test | 6108380 |
| | 6108382 |
| Chlamydia pneumoniae IgA Micro-IF test | 6108390 |
| | 6108392 |
| Chlamydia pneumoniae Micro-IF slides | 6108384 |
| Chlamydia trachomatis IgG EIA | 6111101 |
| Chlamydia trachomatis IgA EIA | 6111111 |
| Biocard™ C. pneumonia IgM | 3-034-000 |
| M. pneumoniae + C. pneumoniae Duplex Real-Time PCR | 8100100 |
| | 8101100 |
| | 8100101 |

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|---|---|
| **Date:** | Valid from: 25 May 2022 |

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